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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|--------------------------|---------------------|------------------|
| 09/840,085 | 04/24/2001 | Alanna Schepartz Shrader | 044574-5099-US | 2186 |

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[REDACTED] EXAMINER

MAHATAN, CHANNING

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 8 |

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------|----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/840,085 | SHRADER ET AL. | |
| Period for Reply | Examiner | Art Unit | |
| | Channing S. Mahatan | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____ .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-22 is/are pending in the application.

 4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) ____ is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input checked="" type="checkbox"/> Other: <i>Attachment for PTO-948</i> . |

DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicants are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

OBJECTION BY DRAFTSMAN

Applicants are hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicants are required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-13 and 19, drawn to polypeptides, classified in class 530, subclass 350. If this group is elected then the below sequence election requirement also is required. Additionally, if this group is elected then the below summarized species election is also required.
- II. Claims 14-18, drawn to a phage-display library, classified in class 435, subclass 91.1. If this group is elected then the below sequence election requirement also is required. Additionally, if this group is elected then the below summarized species election is also required.

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- III. Claim 20, drawn to nucleic acids, classified in class 536, subclass 23.1. If this group is elected, then the below sequence election requirement also is required.
- IV. Claim 21, drawn to a method of preparing a miniprotein, classified in class 435, subclass 69.1; class 530, subclass 333. If this group is elected, then the below sequence election requirement also is required.
- V. Claim 22, drawn to method of identifying a miniprotein, classified in class 435, subclass 4. If this group is elected, then the below sequence election also is required.

SEQUENCE ELECTION REQUIREMENT APPLICABLE TO ALL GROUPS

In addition, each Group detailed above reads on patentably distinct sequences.

Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect one (1) nucleic acid sequence (See M.P.E.P. § 803.04). It is noted that this is a restriction requirement to a single sequence and NOT a species election requirement.

M.P.E.P. § 803.04 states:

“Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.”

It has been determined that one (1) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the

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election of one (1) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

The inventions are distinct, each from the other because:

The inventions of Groups (I and IV), Group (II and V) and Group (III) are independent inventions because they are directed to different chemical types and compositions regarding the critical limitations therein. For Groups I and IV the critical feature is polypeptide; for Group (II and V) the critical feature is phage display library; and for Group III the critical feature is nucleic acids. It is acknowledged that various processing steps may cause a polypeptide of Groups I and IV to be directed as to its synthesis by a polynucleotide of Group III, however, the completely separate chemical types of the inventions of the polypeptide and nucleic acid types Groups supports the undue search burden if any combination of Groups were examined together. Additionally, polypeptide, phage display libraries, and nucleic acids have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I and IV); (II and IV); and (III) are independent and/or distinct invention types for restriction purposes.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group I can be used in the distinct process of the invention of Group V method of preparing a miniprotein. Alternatively, the polypeptides of Group I can be used in a method of diagnosing or prognosing a disease based on the expression or activity of the polypeptide, which is also a clearly distinct usage of the polypeptides.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the phage library of Group II can be used in the distinct process of the inventions of Group IV. Alternatively, the phage library of Group II can be used to construct antibodies, which is also a clearly distinct usage of the phage library.

SPECIES ELECTION REQUIREMENT APPLICABLE ONLY IF EITHER GROUP I OR II IS ELECTED

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. basic region leucine zipper structures (GCN4, CEBP, Max, Myc, and MyoD), claim 7
- B. basic-helix-loop-helix structures ((double minute two, Bcl-2, protein kinase A, Jun, and Fos), claim 12

Currently, claims 1-6, 8-11, and 13-18 are generic to the above Species A and B. The following are definitions to the above distinct species, which justifies and forms the basis of the species election requirement: A. The leucine zipper consists of one amphipathic helix, wherein

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one face of the helix contains side chains that are hydrophilic while the other face contains side chains that are hydrophobic. B. The helix-loop-helix consists of a set of two amphipathic helices separated by a non-helical loop. Although, the claims are directed to groups of known proteins said proteins are utilized in the substitution of residues resulting in a modified polypeptide. Further, each group of proteins belongs to separately distinct classes of proteins (Species A and B as defined above), which are of differing structural characteristics (motifs). Thus, the search burden for the above species are reasonably non-overlapping thus documenting this species election requirement due to an undue search burden that would exist if the search for the prior art covered this reasonably non-overlapping species together.

Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

INVENTORSHIP AMENDMENT

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *July 1, 2002*
Examiner Initials: *CSM*

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER